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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,496	01/11/2001	Bernard Delobel	199463US/XPC	1391

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EXAMINER	
COLLINS, CYNTHIA E	
ART UNIT	PAPER NUMBER
1638	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/674,496	DELOBEL ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13,18-20 and 27-31* is/are pending in the application.

4a) Of the above claim(s) *31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13,18-20 and 27-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's submission filed on October 17, 2006 has been entered.

Claims 1-12, 14-17 and 21-26 are cancelled.

Claim 13 is currently amended.

Claim 31 is withdraw-currently amended.

Claims 13, 18-20 and 27-31 are pending.

Claims 13, 18-20 and 27-30 are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Election/Restrictions

Applicants reiterate their request for the withdrawal of Claim 31 for being drawn to a non-elected invention. The claimed method for protecting plants (Claim 13) and the claimed method for protecting cereal seeds or products derived from cereal seeds (Claim 31) both utilize the same polypeptides of the present invention. Applicants maintain, therefore, that it would not be an undue burden to search the prior art to identify all references that disclose the utilization of polypeptides defined by formula I for killing insect pests to protect plants and to protect products derived reply page 8 from plants. Claim 31 has been amended in the event that the Examiner finds the withdrawal improper. (reply pages 8-9)

Applicants' arguments are unpersuasive, as the elected method utilizes a different material (plants) from the withdrawn method (which utilizes cereal seeds or products derived

from cereal seeds). Examination of the withdrawn method would require an additional search directed to the general use of insecticidal polypeptides to protect cereal seeds or products derived from cereal seeds, as well as to the specific use of polypeptides defined by formula I to protect cereal seeds or products derived from cereal seeds, which additional search would be an undue burden.

Claim Objections

Claim 13 is objected to because of the following informalities: Claim 13 inadvertently recites part of the text of Applicants' response in lines 4-5. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 13 and 18-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record.

Applicants' arguments filed October 17, 2006 have been fully considered but they are not persuasive.

Applicants maintain that the rejection is not believed to be applicable in light of the claim amendments submitted herein, that is, the N-terminal sequence of the pea PA 1 b albumin protein. Applicants maintain that the source species and a defining structural feature coupled with functional language, e.g., insecticidal activity, has been provided in the amended claims,

and that the application unquestionably describes the activity of such a polypeptide as an insecticide. Applicants further note that the inclusion of Claims 27-30 in the enablement rejection appears to be a mistake as each of these claims define specific sequences of the protein. Applicants point out that in Figure 4 of Example 1 of the specification, mortality rates for oryzae weevils exposed to at least 9 different types of legumes are provided (see page 9, lines 27- 37), and that the specification therefore unquestionably describes the polypeptides utilized in the claimed methods and demonstrates Applicants' possession of the claimed invention. (reply pages 7-8)

The Examiner maintains that the specification does not describe a representative number of species of insecticidal proteins that meet the structural limitations of the claims, as the specification does not describe a representative number of polypeptides resulting from the claimed formula as amended, because only a single amino acid sequence of a single insecticidal protein resulting from the claimed formula, the TP polypeptide obtained from pea, is described. With respect to Figure 4, the Examiner maintains that the mortality rates for oryzae weevils exposed to at least 9 different types of legumes do not describe the broad genus of peptides recited in the claims because the structure(s) of the legume agent(s) responsible for the mortality rates for oryzae weevils are not disclosed. With respect to Applicants assertion of possession, the Examiner maintains that a showing of possession alone is not sufficient to meet the written description requirement. See *Enzo Biochem Inc. v. Gen-Probe Inc.*, 63 USPQ2d 1609, 1617:

> Application of the written description requirement, however, is not subsumed by the "possession" inquiry. A showing of "possession" is ancillary to the *statutory* mandate that "[t]he specification shall contain a written description of the invention," and that requirement is not met if, despite a showing of possession, the specification does not adequately describe the claimed invention. After all, as indicated above, one can show possession of an invention by means of an affidavit or declaration during prosecution, as

> one does in an interference or when one files an affidavit under 37 C.F.R. § 1.131 to antedate a reference. However, such a showing of possession alone does not cure the lack of a written description in the specification, as required by statute.

Applicants also maintain that the specification as filed provides sufficient instruction to enable a person skilled in the art to make and use the invention commensurate in scope with Claims 13 and 31. Figure 4 of Example 1 of the specification (see page 9, lines 27- 37) provides mortality rates for oryzae weevils exposed to several types of legumes tested, including cowpea (Vigna unguiculata), white and red bambora groundnut (Vigna subterranea), lentil (Lens esculenta), french bean (Phaseolus vulgaris), mung bean (Vigna radiata), adzuki bean (Vigna angularis), broad bean (Viciafaba), chickpea (Cicer arietinum), and lupin (Lupinus albus). Because all legumes tested were toxic against a sensitive strain of weevils but not against a resistant strain, the Applicants reasonably concluded from the results that the same mechanism for causing insect toxicity is involved in all legumes tested (see page 10, lines 1-16). The toxicity assay provided in Example 1 can be applied to any plant of interest in order to determine the mortality curve or pattern for a given insect pest so that polypeptide candidates having insecticidal activity and comprising a motif defined by formula I insecticidal activity in plant samples tested according to the method disclosed in Example 1. (reply page 8)

With respect to Applicants assertion of that the specification as filed provides sufficient instruction to enable a person skilled in the art to make and use the invention commensurate in scope with Claims 13 and 31, the Examiner maintains that an enabling disclosure is not necessarily descriptive of a genus of sequences. See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), which discusses the description of a claimed

human cDNA sequence based on the disclosure of a rat cDNA sequence and a method for obtaining the human cDNA sequence:

> The patent describes a method of obtaining this cDNA by means of a constructive example, Example 6. This example, however, provides only a general method for obtaining the human cDNA (it incorporates by reference the method used to obtain the rat cDNA) along with the amino acid sequences of human insulin A and B chains. Whether or not it provides an enabling disclosure, it does not provide a written description of the cDNA encoding human insulin, which is necessary to provide a written description of the subject matter of claim 5. The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. (*Lilly*, 43 USPQ2d at 1405)

For information purposes, Applicants have additionally attached is a draft of an article that has been recently submitted for publication (Petit et al), which demonstrates the insecticidal activity of 2 isoforms of pea PAlb (AJ574794 and AJ574795) which are different of both the PT and the Paib protein disclosed in the present application. This document contains a reference to an US patent (5,955,082) and its Canadian counterpart, which disclose an insecticidal composition comprising "the protein-rich fraction of a legume extract". This U.S. patent is cited in the attached IDS. The active ingredient of this protein-rich fraction is not believed to be a PAlb albumin, in particular because its activity is destroyed by heating at 100°C (example 6 of US 5,955,082), which is not the case for the PAl b albumins (page 14, lines 33-37 of the instant application). (reply page 9)

With respect to the attached is a draft article, its relevance to the outstanding rejection is not apparent, as Applicants assert that the 2 isoforms of pea PAlb "are different of both the PT and the Paib protein disclosed in the present application" and that the active ingredient of a

protein-rich fraction disclosed in a US patent (5,955,082) and its Canadian counterpart is not believed to be a PAlb albumin.

Claims 13, 18-20 and 27-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of protecting a plant from insects comprising treating the plant with a composition comprising a polypeptide having a sequence of the disclosed TP polypeptide, does not reasonably provide enablement for methods comprising treating the plant with other compositions comprising other polypeptides having other sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record.

Applicants' arguments filed October 17, 2006 have been fully considered but they are not persuasive.

Applicants maintain that the rejection is not believed to be applicable in light of the claim amendments submitted herein, that is, the N-terminal sequence of the pea PA 1 b albumin protein. Applicants maintain that the source species and a defining structural feature coupled with functional language, e.g., insecticidal activity, has been provided in the amended claims, and that the application unquestionably describes the activity of such a polypeptide as an insecticide. Applicants further note that the inclusion of Claims 27-30 in the enablement rejection appears to be a mistake as each of these claims define specific sequences of the protein. Applicants point out that in Figure 4 of Example 1 of the specification, mortality rates for oryzae weevils exposed to at least 9 different types of legumes are provided (see page 9, lines 27- 37),

and that the specification therefore unquestionably describes the polypeptides utilized in the claimed methods and demonstrates Applicants' possession of the claimed invention. (reply pages 7-8)

Applicants also maintain that the specification as filed provides sufficient instruction to enable a person skilled in the art to make and use the invention commensurate in scope with Claims 13 and 31. Figure 4 of Example 1 of the specification (see page 9, lines 27- 37) provides mortality rates for oryzae weevils exposed to several types of legumes tested, including cowpea (Vigna unguiculata), white and red bambora groundnut (Vigna subterranea), lentil (Lens esculenta), french bean (Phaseolus vulgaris), mung bean (Vigna radiata), adzuki bean (Vigna angularis), broad bean (Viciafaba), chickpea (Cicer arietinum), and lupin (Lupinus albus). Because all legumes tested were toxic against a sensitive strain of weevils but not against a resistant strain, the Applicants reasonably concluded from the results that the same mechanism for causing insect toxicity is involved in all legumes tested (see page 10, lines 1-16). The toxicity assay provided in Example 1 can be applied to any plant of interest in order to determine the mortality curve or pattern for a given insect pest so that polypeptide candidates having insecticidal activity and comprising a motif defined by formula I insecticidal activity in plant samples tested according to the method disclosed in Example 1. (reply page 8)

The Examiner maintains that the disclosure of a single amino acid sequence of a single insecticidal protein resulting from the claimed formula, the TP polypeptide obtained from pea, does not enabled the full scope of the claimed invention in light of the unpredictability of the sequence variants retaining the functional characteristics of the TP protein. With respect to the inclusion of Claims 27-30 in the enablement rejection, Claims 27-30 are included because

insectcidal activity for these specific amino acid sequences has not been established. With respect to Figure 4, the Examiner maintains that the mortality rates for oryzae weevils exposed to at least 9 different types of legumes does not provide guidance with respect to which of the polypeptide sequence variants recited in the claims would have insecticidal activity and which would not.

For information purposes, Applicants have additionally attached is a draft of an article that has been recently submitted for publication (Petit et al), which demonstrates the insecticidal activity of 2 isoforms of pea PAlb (AJ574794 and AJ574795) which are different of both the PT and the Paib protein disclosed in the present application. This document contains a reference to an US patent (5,955,082) and its Canadian counterpart, which disclose an insecticidal composition comprising "the protein-rich fraction of a legume extract". This U.S. patent is cited in the attached IDS. The active ingredient of this protein-rich fraction is not believed to be a PAlb albumin, in particular because its activity is destroyed by heating at 100°C (example 6 of US 5,955,082), which is not the case for the PAl b albumins (page 14, lines 33-37 of the instant application). (reply page 9)

With respect to the attached is a draft article, its relevance to the outstanding rejection is not apparent, as Applicants assert that the 2 isoforms of pea PAlb "are different of both the PT and the Paib protein disclosed in the present application" and that the active ingredient of a protein-rich fraction disclosed in a US patent (5,955,082) and its Canadian counterpart is not believed to be a PAlb albumin.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Remarks

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cynthia Collins
Primary Examiner
Art Unit 1638

CC

1/5/07